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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,534	08/28/2000	Sylviane Gabrielle Nadine Dennler	1430-245	4173

7590

04/09/2002

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,534

Applicant(s)

DENNLER ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The examiner of the application has changed. This case has now been transferred as of April 3, 2002. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher Yaen, Group Art Unit 1642.
2. Amendments filed on July 24, 2001 (paper no.12) and January 4, 2002 (paper no 17) and have been entered and will be considered. Sequence rules compliance under 37 CFR 1.821(a)(1) and (a)(2) has been met and amendments to the specification have been entered. Claim 5 has been canceled without prejudice and claims 1-4, and 6 are being examined on the merits.

Claim Rejections Withdrawn- 35 USC § 112

3. The rejection of claims 1-6 under 35 USC §112, second paragraph, are **withdrawn**, in view of the amendments made and arguments set forth by the applicant.

Claim Rejections Maintained- 35 USC § 112

4. The rejection of claims 1-6 under 35 USC §112, first paragraph, as not lacking scope of enablement, is **maintained**, for the reason stated in the previous office action (paper no 11.) Applicant argues that following amendment to claims 1 and 6, the newly recited claims do not read on all Smads, and that the newly recited claims do not "*directly cover methods of treating diseases, but merely provide tools for identifying agents that could be used for such treatment*". Although the newly recited claims clarified the issues with regards to scope of enablement of Smads (now reading only on

Smad 2 spliced in exon 3, Smad3 and Smad 4), the claims still read upon the use of these agents for the treatment of the instantly claimed diseases. By the recitation of "therapeutic", the method connotes to one of skill in the art that the method of screening is to be used to identify agents that can be used to treat the said diseases. In addition, the recitation of such a term prevents those who actually have an agent that is capable of preventing the interaction between a Smad (namely Smad 2 spliced from exon 3, Smad 3 and Smad 4) and a DNA sequence containing a CAGA domain from using it towards the treatment of the claimed diseases. Furthermore, as cited in a prior office action, the specification is silent with regard to using the discovered agent in an *in vivo* context and that using such would force the skilled artisan into undue experimentation. For these reasons and the reasons stated in the prior office action, this rejection is maintained.

Claim Rejections Maintained- 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The rejection of claims 1-6 under 35 USC§103, as being obvious over Yingling *et al.*, is **maintained**, for the reasons of record. The applicant's arguments are considered but are not found persuasive for the following reasons. The method is drawn to a method of screening for a therapeutic agent that interferes between the interaction of Smads and CAGA domain of promoters. Applicant argues that Yingling *et al.* teach away from the instantly claimed invention in that the Smad binding domain is not necessary for TGF-beta induced signaling. Although the disclosure as taught by

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Yingling *et al.* does describe a result that opposes that taught by the instant application, the claim reads on the screening of an agent using a oligonucleotide sequence that comprises WXYCAGACZ, wherein a W is either an A or G, X is either G or T, and Y is C, A, G, or T, and Z is either A or C. Yingling *et al.* disclose of a method to determine responsiveness of Smads to TGF-beta stimulation, wherein the binding of a Smad is to an oligonucleotide, that comprises the WXYCAGACZ sequence, wherein the W is a A, X is a G, Y is a T, and Z is an A (see figure 3A). The oligonucleotide, used in the instantly claimed invention, is found in the oligonucleotide used by Yingling *et al.*, and because the claims are drawn to a nucleotide which comprises the sequence WXYCAGACZ, the method to screening instantly claimed is obvious over the prior art. As stated in the prior office action (paper no 11), the disclosure set forth by Yingling *et al.* do not disclose of screening for an agent, the methodological steps are similar. For these reasons, the rejection of claims 1-6 under 35 USC103(a) is maintained.

Conclusion

7. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
April 5, 2002


ANTHONY C. CAPUTA
SUPERVISOR, PATENT EXAMINER
TECHNICAL CENTER 1642